L3.

Off-the-Shelf Fenestrated Stent Graft: One-Year Prospective Results from Multiple p-Branch Single-Center Clinical Trials

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Objectives: To present prospective aggregated data of an off-the-shelf (OTS) fenestrated endograft (Zenith® p-Branch™) from 4 centers for the treatment of patients with juxtarenal or pararenal abdominal aortic aneurysms.

Methods: The p-Branch™ endograft consists of a proximal, OTS component incorporating a scallop for the celiac artery, a superior mesenteric artery (SMA) fenestration, and two conical-shaped pivot fenestrations to preserve flow to the renal vessels. The device is available in two configurations; a left renal fenestration at the same (A) or lower (B) longitudinal position than the right renal fenestration, to accommodate varied patient anatomies. One-year results with a data cutoff of November 21, 2013 are presented.

Results: Of 54 patients (81% male; mean age, 72 years; 47 elective and seven emergent) enrolled, 57% were implanted with option A, and 43% with B. The device was deployed successfully in all patients and stents placed in all target vessels except in two emergent cases: a left kidney was sacrificed in one patient and a right renal artery was unstented in one patient during the index procedure. There were no deaths, ruptures, or conversions to open repair. One emergent patient had a site-reported type I endoleak; no other type I/III endoleaks were observed. One patient experienced bowel ischemia that resolved with nonoperative treatment. Renal artery occlusion/severe stenosis occurred in six patients (11%) deemed procedure-related by the implanting physician in 83% of the patients. Four (67%) of these were successfully intervened upon with preservation of renal function. The overall renal insufficiency incidence was 4%. No patient developed renal failure requiring dialysis.

Conclusions: Early results incorporating physician learning curves with a new device and delivery system indicate that the use of the Zenith p-Branch device is feasible and safe. Long-term follow-up is needed to assess the effectiveness and durability of this treatment strategy and refine the indications for use.

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L4.

One-Year Results of the Terumo Anaconda One-Lok Trial for Endovascular Aneurysm Repair

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Objectives: To describe the 1 year (yr) results of the Terumo Anaconda ONE-LOK Stent Graft System Phase II IDE Study for the treatment of infrarenal abdominal aortic aneurysm (AAA)

Methods: This Investigational Device Exemption (IDE) trial enrolled 195 patients at 23 sites in the US and Canada between June 2009 and May 2012. Outcomes were compared with the historical open surgical controls from the Society for Vascular Surgery (SVS) registry. Chi-squared analysis, Fishers exact test and Kaplan-Meier analysis were performed.

Results: The primary safety endpoint was met with 95.9% freedom from major adverse events (MAE) at 30 days defined as all-cause mortality, myocardial infarction (MI), renal failure (RenF), respiratory failure (RespF), paralysis or paraplegia, cerebrovascular accident, and bowel ischemia. There was 1 nonaneurysm-related mortality, 5 MI, and 2 patients with RespF. Secondary safety end points include incidence of MAEs at 1 yr and freedom from abdominal aortic aneurysm (AAA) related mortality at $\leq$ 30 and $\leq$ 365 days. There was no AAA rupture or AAA-related mortality with 1 yr all-cause mortality of 3.1% (six patients). Other MAEs were 7 MI (3.6%), 2 RenF (1.0%), and 2 RespF (1.0%). Technical success through the first 24 hrs was 96.9%. Primary efficacy of EVAR at 1 yr was 93%. 96.4% of patients experienced aneurysm sac shrinkage or stabilization at 1 yr. Limb occlusions occurred in seven patients (3.6%) at 1 yr. Five (2.6%) type I endoleaks were treated; no Type III endoleaks were treated. 3.6% percent of pts had type II endoleaks requiring treatment. Freedom from secondary interventions was 99.5% at 30 days and 95.1% at 1 yr.

Conclusions: EVAR performed using the Terumo Anaconda One−Lok stent graft system is safe and effective at preventing AAA related death when compared with open repair, with minimal need for reintervention at 1 yr.

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L5.

Endovascular Repair for Blunt Thoracic Aortic Injury with Zenith TX2 Low Profile Device

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Objectives: To report 30-day results from a prospective, nonrandomized, multicenter study that evaluated the safety and effectiveness of the Zenith TX2 Low Profile Endovascular Graft (TX2-LP, Cook Medical, Bloomington IN) for treatment of blunt thoracic aortic injuries.

Methods: The TX2-LP device is available in smaller graft diameters (starting at 18 mm) and lower profile delivery systems (starting at 16 Fr) than currently available thoracic endografts. The device (nitinol stents and polyester graft material) accommodates a tighter aortic curvature (radius of 20 mm) than the predicate TX2 Pro-Form. Primary endpoint was 30-day mortality.

Results: Between January 2013 and March 2014, 44 patients (40 men; mean age, 43 ± 19 years, range, 18-89 years) were treated at 17 US sites. The mean injury severity score was 30 ± 13 (range, 6-66). Technical success was achieved in 100% of patients, with 0% intraoperative mortality. Device access was entirely percutaneous in 17 patients (39%). Smaller size grafts (18-24 mm) were used in 15 patients (34%). The mean procedure time was 83 ± 46 minutes (range, 34-278 minutes), and mean blood loss was 109 ± 152 cc (range, 0-1000 cc). The 30-day mortality rate was 2%: one patient died 24 days postprocedure from respiratory failure related to associated injuries and not to the device or procedure as adjudicated by an independent clinical events committee (CEC). One patient experienced incomplete quadriplegia on the day of the procedure (CEC adjudication pending) and one patient experienced a stroke 7 days postprocedure (cause undetermined by the CEC). One patient underwent reintervention for a site-reported proximal type I endoleak (core lab reported unknown endoleak type) at 30 days postprocedure. There have been no conversions to open surgical repair.

Conclusions: Short-term results indicate that the TX2-LP device appears safe and effective for the treatment of blunt thoracic aortic injuries. Further enrollment and follow-up are ongoing.

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L6.

Five-Year Results of the United States Multicenter Prospective Study Evaluating the Zenith® Fenestrated Endovascular Graft for Treatment of Juxtarenal Abdominal Aortic Aneurysms

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Objectives: This study reports results of a prospective, multicenter trial designed to evaluate the safety and effectiveness of the Zenith® Fenestrated AAA Endovascular Graft (ZFEN, Cook Medical, Bloomington IN) for treatment of juxtarenal abdominal aortic aneurysms (AAAs).

Methods: Sixty-seven patients with juxtarenal AAAs were prospectively enrolled in 14 U.S. centers (2005-2012). Custom-made fenestrated stent-grafts were designed with up to three fenestrations based on analysis of computed tomography (CT) datasets. Renal alignment was performed using balloon-expandable stents. Follow up included clinical examination, laboratory studies, duplex ultrasound, abdominal X-rays and CT imaging at hospital discharge, 1, 6, 12 months, and yearly thereafter up to 5 years.

Results: here were 54 male and 13 female patients with a mean age of 74±8 years old enrolled. Mean aneurysm diameter was 60 ± 10 mm. A total of 178 visceral arteries required incorporation with small fenestrations in 118, scallops in 51 and large fenestrations in 9. Of these, all 118 small fenestrations (100%), 8 of the scallops (16%), and 1 of the large fenestrations (11%) were aligned by stents. Technical success was 100%. There was one postoperative death within 30 days (1.5%). Mean length of hospital stay was 3 ± 2 days. There were no type I or III endoleaks, aneurysm ruptures or conversions noted during a mean follow up of 37 ± 17 months (3-65 months). Two patients (3%) had migration >5 mm with no endoleak due to cranial progression of aortic disease. Of a total of 129 renal arteries targeted by a fenestration, there were 4 (3%) renal artery occlusions and 10 (8%) stenoses. Fifteen patients (22%) required secondary interventions for renal artery stenosis/occlusion in 11 patients, type II endoleak in three and indeterminate endoleak in one. At 5 years, patient survival was 91% ± 4%, freedom from major adverse events was 79% ± 6%, primary and secondary patency of targeted renal arteries was 81±5% and 97% ± 2%, freedom from renal function deterioration was 91±5%, and freedom from secondary interventions was 63% ± 9%.

Conclusions: This prospective study demonstrates that endovascular repair of juxtarenal AAAs using ZFEN is safe, effective and durable. Mortality and morbidity are low in properly selected patients treated in centers with experience in these procedures.

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†In memoriam